

## **DETAILED ACTION**

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission of the claim amendment filed on 05/20/2011 has been entered. Upon entering the submission, claims 1-5, 14, and 25-27 are currently pending.

### ***Declaration under Rule 37 C.F.R. §1.132***

Applicants' submission of the Declaration under Rule 37 C.F.R. §1.132, filed on 05/20/2011 **is not entered**, because the Declaration is **not** signed by the person who made the Declaration.

### ***Response to Arguments***

#### **Argument over rejection of claims under 35 U.S.C. §103(a)**

The Declaration filed on 05/20/2011 under 37 CFR 1.132 has not been entered because it is not signed by the person who made the Declaration.

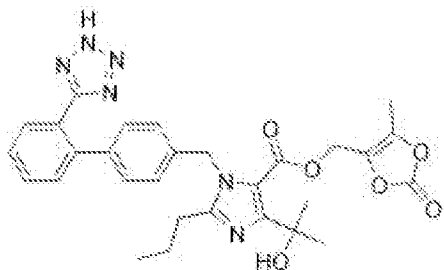
In response to the Office action, Applicants argued that the Examiner has provided no evidence that the person of ordinary skilled in the art would have selected compound I-b-40 from Maetzke as a lead compound. Applicants argued that there is no discussion in *Daiichi* whether there is one versus two structural differences. The key issue is whether one skilled in the art would have selected a certain embodiment in the

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cited art as a "lead compound." Applicants further argued that according to *Daiichi*, the Examiner must provide evidence that a person of ordinary skill in the art, examining Maetzke as a whole, would have chosen Compound I-b-40 as a lead compound from among hundreds of compounds in Maetzke. Applicants' arguments have been fully considered, but are not sufficient to overcome the 103a rejection for the following reasons:

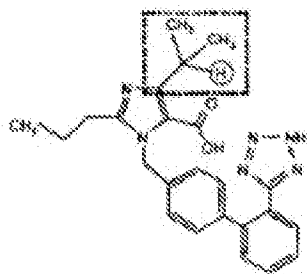
a) The 132 Declaration on 05/20/2011 is defective because it is not signed, therefore the unexpected results of the elected species of compound (I-1-a-2) over the selected lead prior art compound (I-b-40) are not recognized.

b) In *Daiichi*, the compound on appeal is Olmesartan medoxomil



, a FDA approved drug for treating high blood pressure.

The alleged closely related lead compound is a compound of '902 Example 6



disclosed in DuPont's U.S. patent 5,137,902. It is not difficult for

one ordinary skilled in the art to tell how the differences between the alleged '902

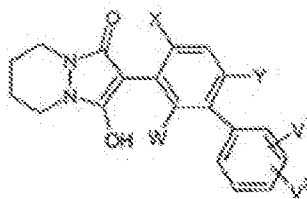
compound and Olmesartan medoxomil in *Daiichi*. It is clear for one ordinary skill in the

art to understand that two compounds are **not obvious** because the differences of the

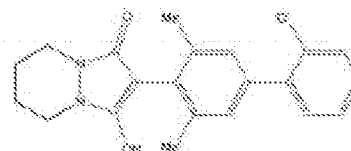
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groups at the 4'- and 5' positions. The Court went further by considering the unexpected results of Olmesartan medoxomil as FDA approved drug with less toxicity and high in vivo efficacy over the `902 compound. Therefore, the Court affirms the validity of the compound Olmesartan medoxomil non-obvious over the `902 compound.

c) In contrast with *Daiichi*, Applicants have not provided **valid** unexpected results of the `902 compound (i.e. I-b-40) over the elected species (i.e. I-1-a-2), and the



other compounds of the formula (I) wherein **W** and **Y** are H or alkyl; **X** is alkyl; **V<sup>1</sup>** is 2-Cl; **V<sup>2</sup>** is H. A patent is presumed valid unless proved otherwise.



The `902 patent teaches the specific compound (i.e. I-b-40) as an herbicide, even though there is no specific testing results disclosed. However, there are only limited number of the specific compounds are disclosed to support the claimed genus, and one ordinary skilled in the art understands the utility of said compounds. Unlike a drug required FDA approval for its high-level pharmaceutical utility, the level of skill as an herbicide is not that high. Therefore it is not necessary for all the compounds are tested and disclosed in the specification in order to demonstrate the possession of the claimed invention. The motivation of modifying the lead compound (i.e. I-b-40) toward the instant claims is structural similarity itself. Compounds with structural similarity possess similar properties is the foundation for

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Markush claims. Compounds which differ only in the placement of substituents in a ring system is not unobvious absent unexpected results. *In re Jones*, 162 F.2d 638, 74 USPQ 152 (CCPA 1947). The motivation to make the claimed compounds derives from the expectation that knowing properties of one member of series compounds would in general know what to expect in adjacent members with similar activity (i.e. as herbicides). Therefore, the instantly claimed compounds would have been suggested to one skilled in the art, and the rejection is **maintained**.

In order to overcome the 103a rejection, Applicants have to file valid 132 Declaration to demonstrate unexpected results over a limited scope of invention as described in the previous Office action on 01/29/2009, see page 3 under "Provisionally Elected and Examined Subject Matter".

#### **Claim Objection**

Claim objection to claims 1-5, 14, and 25-27 is maintained because they still contain non-elected subject matter.

#### ***Conclusions***

- Claims 1-5, 14, and 25-27 are rejected.
- Claims 1-5, 14, and 25-27 are objected to.

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***Telephone Inquiry***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yong Chu, Ph.D., whose telephone number is 571-272-5759. The examiner can normally be reached between 7:00 am - 3:30 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph K. McKane can be reached on 571-272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Yong Chu/  
Primary Examiner  
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